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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,954	03/19/2004	Marise S. Gottlieb		8077

7590 08/23/2006

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,954

Applicant(s)

GOTTLIEB, MARISE S.

Examiner

Marcela M. Cordero Garcia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-7, in the reply filed on June 9, 2006 is acknowledged. The traversal is on the ground(s) that the classification is not proper, and that in groups I-VI there is overlapping subject matter. This is not found persuasive for the reasons set forth in the Office Action dated May 9, 2006 and because even when a group belongs to the same classification it does not imply that it can be searched concurrently, e.g., within the non-patent literature. As previously stated on page 3 of the previous Office Action, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case and the search required for each Group is not necessarily required for the other Groups. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of the species "YG Product" as the composition used and "obesity associated with the Metabolic Syndrome" as the chronic inflammation to be treated the reply filed on May 9, 2006 is acknowledged. The traversal is on the ground(s) that all the members of the Markush group are sufficiently few in number or so closely related to a search

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and examination of the entire claim and that the subject matter has unity of invention. This is not found persuasive because the many embodiments of compounds and diseases to be treated necessitate distinct searches and consideration and because unity of invention is relevant only in national stage cases and this case is not within such category.

The requirement is still deemed proper and is therefore made FINAL.

The species elected by Applicant ("YG Product" as the composition used and "obesity associated with the Metabolic Syndrome") was searched and found free of the prior art (however please see double patenting rejection below). Examiner elected a new species from amongst the instantly claimed invention for examination, namely "YG Product" as the composition used and "rheumatoid arthritis" as the chronic inflammation disease to be treated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 is rejected under 35 U.S.C. 102(b) as being anticipated by Gottlieb (EP 0230 052 A2) as evidenced by Persselin (Clin Orthop Relat Res, 1991).

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Gottlieb teaches a method for controlling rheumatoid arthritis in an individual, comprising administering to said individual an effective dosage of a pharmaceutical composition of YG-Product (e.g., abstract, lines 6-14).

Persselin evidences that rheumatoid arthritis is inherently a chronic systemic inflammatory disease (page 73, column 1, lines 1-3) and that elevated C-reactive protein levels and platelet counts serve as indicators of disease activity (e.g., abstract, lines 20-23).

Therefore, the reference is deemed to anticipate the instant claims above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-10 of U.S. Patent No. 4,699,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a method for controlling chronic inflammation (e.g., cancer, example 6, claims 7-10 of US '898) in an individual comprising: administering to said individual an effective dosage of a pharmaceutical composition selected from the group consisting of YGG-Product (Please note that TGG and YGG are equivalent terms, e.g., column 12, lines 48-60 of US '898). Further, the instantly claimed method encompasses and/or is encompassed by the claimed method of US '898.

Claims 1-3 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8 and 13 of U.S. Patent No. 4,710,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to a method for controlling chronic inflammation (e.g., rheumatoid arthritis or diabetes, claims 4 and 8 or US '380) in an individual comprising: administering to said individual an effective dosage of a pharmaceutical composition selected from the group consisting of YGG-Product (claim 13 of US '380). Please note that TGG and YGG are equivalent terms as stated above. Further, the instantly claimed method encompasses and/or is encompassed by the claimed method of US '380.

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Claim Objections

Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

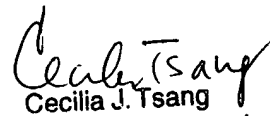
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1654

MMCG 08/06



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